Evolution

A Physician initiated trial investigating the efficacy of the self-expanding iVolution nitinol stent for the treatment of femoropopliteal lesions.

ClinicalTrial.gov identifier	NCT02430922
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Graph 1 : Enrollments per center

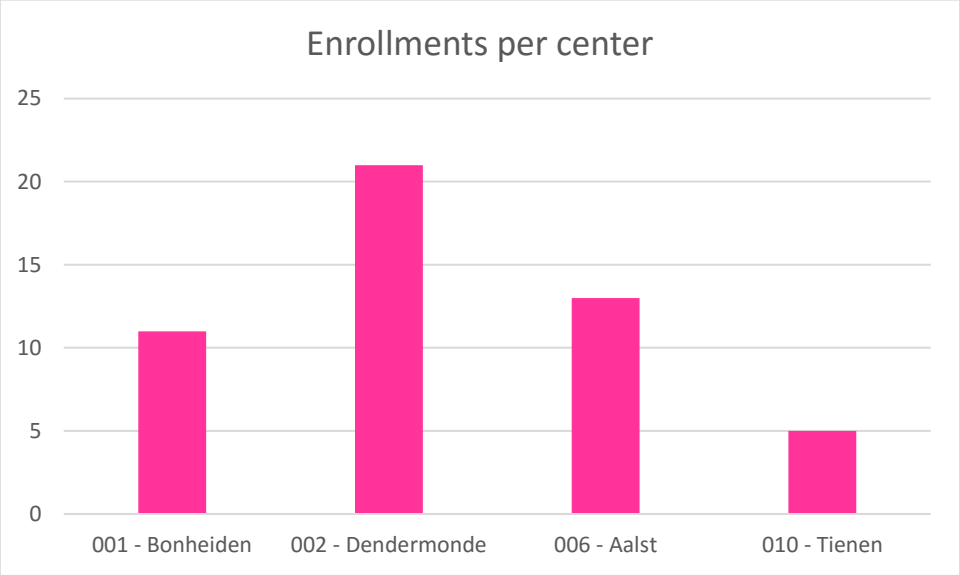


Table 1 : Patient characteristics

Male (%) Female (%)	35 (70.00%) 15 (30.00%)
Age (min – max ; SD)	70.81 years (50.23 – 89.47 ; ± 9.47)
Nicotine Abuse? - Yes - No - Quit	 - 18 (36.0 %) - 21 (42.0 %) - 13 (26.0 %)
Hypertension? - Yes - No	 - 33 (66.00 %) - 17 (34.00 %)
Diabetes Mellitus? - Yes, Type I - Yes, Type II - No	 - 7 (14.00 %) - 3 (6.00 %) - 40 (80.00 %)
Renal Insufficiency? - Yes - No	 - 6 (12.0 %) - 44 (88.00 %)
Hypercholesterolemia? - Yes - No	 - 26 (52.00 %) - 24 (48.00 %)
Obesity? - Yes - No	 - 12 (24.00 %) - 38 (76.00 %)

Rutherford 2	15 (30.00 %)
Rutherford 3	29 (58.00 %)
Rutherford 4	6 (12.00 %)

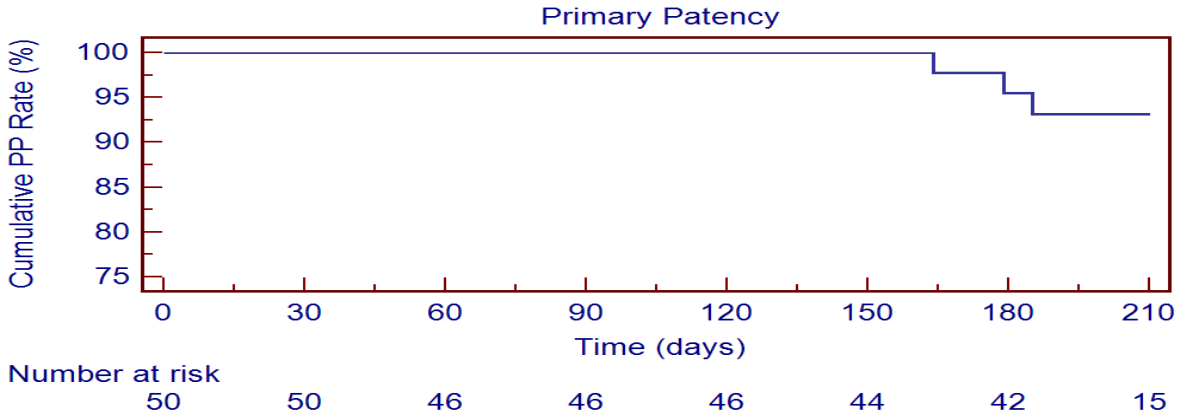
Table 2 : Procedure characteristics

Procedure Duration	42.04 minutes (16 – 109 ; ± 17.57)
Access Side - Left CFA - Right CFA	 - 29 (58.00 %) - 21 (42.00 %)
Cross over performed? - Yes - No	 - 46 (92.00 %) - 4 (8.00 %)
Scopy time	10.65 minutes (3.4 – 70 ; ± 9.86)
Contrast dose	78.16 mL (15 – 200 ; ± 37.90)

Left Limb / Right Limb	18 / 32
Lesion length	87.46 mm (9 – 150 ; ± 46.97)
RVD	5.58 mm (5 – 7 ; ± 0.60)
MLD	0.51 mm (0 – 2,5 ; ± 0.63)
occlusion	24 (48.00 %)
Calcified lesion	31 (62.00%)
Inflow lesion treated? - Yes - No	 - 10 (20.00%) - 40 (80.00%)
Outflow lesion treated? - Yes - No	 - 4 (8.00 %) - 46 (92.00 %)

Primary Patency

Primary Patency Rate at 6-month is 93.20%. 3 Patients lost primary patency within the first 6 months. 2 patients had complaints (raise in Rutherford, drop in ABI), 1 patient had no clinical symptoms but PSVratio >2.4



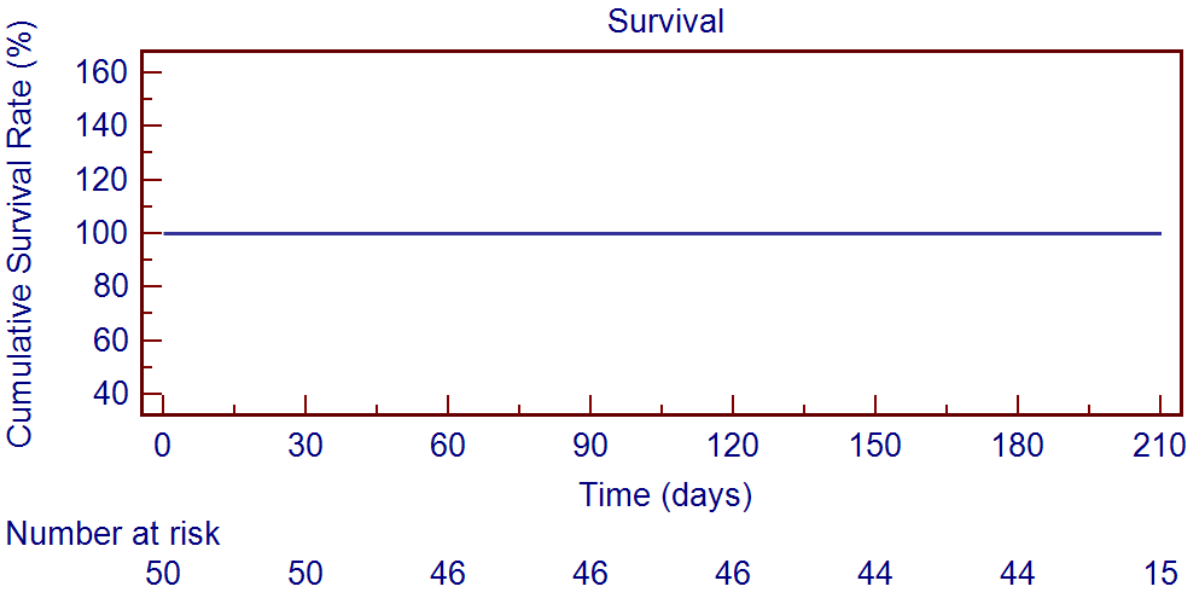
Survival time	tar_PP
Endpoint	PP

Sample size	50
Median survival	434

Survival time	Survival Proportion	Standard Error
37	-	-
121	-	-
138	-	-
164	0,977	0,0225
179	0,955	0,0314
185	0,932	0,038
210	-	-
214	-	-
216	-	-
219	-	-
224	-	-
227	-	-
232	-	-
239	-	-
253	-	-
303	0,777	0,145
395	-	-
434	0,000	0,000

SURVIVAL

None of the patient died within the first 6 months. Survival rate was 100%.



Survival time	tar_SURV
Endpoint	SURV

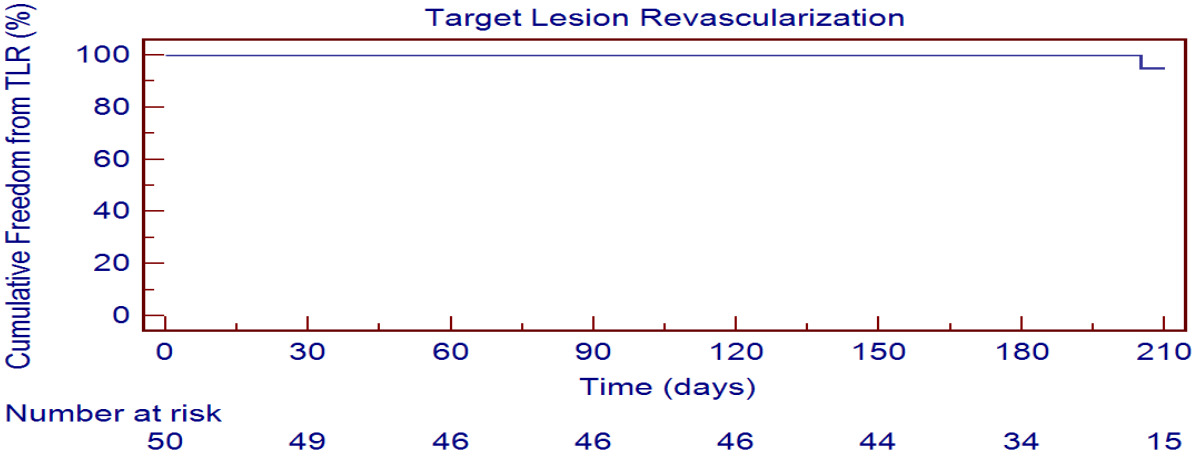
Sample size	50
Median survival	-

Survival time	Survival Proportion	Standard Error
37	-	-
121	-	-
138	-	-
210	-	-
214	-	-
216	-	-
219	-	-
224	-	-
227	-	-
232	-	-
239	-	-
253	-	-
311	-	-
395	-	-
439	-	-

Freedom from Target Lesion Revascularization

At day 205 (within the 6MFU time window), one patient had a revascularization of the target lesion, resulting in a freedom from TLR of 95.0% at 6 month. The second patient with complaints also had a TLR, but at day 253 and therefore outside the 6MFU time window.

TLR



Survival time	tar_TLR
Endpoint	TLR

Sample size	50
Median survival	439

Survival time	Survival Proportion	Standard Error
23	-	-
31	-	-
34	-	-
37	-	-
121	-	-
138	-	-
162	-	-
163	-	-
164	-	-
166	-	-
176	-	-
177	-	-
179	-	-
180	-	-
185	-	-
187	-	-
189	-	-
194	-	-
195	-	-
199	-	-
202	-	-
203	-	-
204	-	-
205	0,950	0,0487
207	-	-
210	-	-
214	-	-
216	-	-